IV.CASE REVIEW

2209

Case Presentations: Structural Heart Disease

Sunday, March 30, 2008, 2:30 p.m.-5:30 p.m.
McCormick Place, Room S106a

3:00 p.m.

2209-8 Experience With CoreValve Aortic Valve Replacement in Patients for Surgical Aortic Valve Replacement

Eberhard Grube, Gerckens Ulrich, Gerhard Schuler, A. Linke, Raoul Bonan, Patrick W Serruys, Peter Dejaegere, J. Kovacs, Peter Den Heijer, M. Labinaz, M. Ruell, M. Mullen, Johan Bosmans, N. Moat, W. Tymchak, A. Bosmans, B. Benit, Montreal Heart Institute, Montreal, QC, Canada, Helios Heart Center, Siegburg, Germany

Background: Percutaneous aortic valve replacement (PAVR) is an emerging alternative to palliative medical therapy for high risk and non-surgical (HR) patients (pts) with severe aortic stenosis (AS). We report the global experience of PAVR with the CoreValve Revalving™ systems (Irvine, Ca, USA), 21 and 18 French, which includes a self-expandable porcine pericardium bioprosthesis within in a multi-level nitinol frame.
Methods: HR pts with symptomatic, severe AS were enrolled. From a multi-disciplinary approach involving general anesthesia, surgical arterial access and femoral-femoral cardiopulmonary bypass, the implantation evolved to a standard percutaneous intervention without any surgical cut-downs or repair and without hemodynamic/cardiac support.
Results: Since August 2005, 175 (112 18Fr system) consecutive HR pts, with severe native aortic stenosis were included. The mean Logistic Euroscore (LEs) was 24.2% mean age 81.6 years, 60% females, mean AVA 0.61 cm^2. Procedural success occurred in 161 pts, 8 prostheses were misplaced, in 3 pts the prosthesis was not implanted after balloon valvuloplasty (access problem with the 21 Fr system), 2 aortic root and 1 left ventricle (wire) perforations happened. 30 days cumulative mortality happened in 26 pts (15%) with mean LEs of 31%. Successful implants showed a post-procedure mean AVA of 1.65 cm^2. In 22% of pts, there were significant immediate paravalvular leaks (grade III-IV: only 2%). Cumulative free survival between 30 days and 2 years is over 82 %. The 18 Fr, third generation device experience showed an evolution toward a complete percutaneous procedure with implantation done without any type of cardiac support or surgical cut-down/repair.
Conclusions: These multi-center studies with two generations of catheters with decreasing size has evolved PAVR towards a pure "cath lab" procedure, showed a definitive learning curve, has lead to a better understanding of the anatomical requirements, provide positive follow-up without bioprosthetic or coronary complications and provide safety and efficacy data for this self-expanding PAVR system in this high risk AS population.

3:15 p.m.

2209-9 Transfemoral Retrograde Edwards-Sapien Aortic Valve Implantation: Angiographic Criteria for Patient Selection

Mehdi Kerkeni, Helene Eltchaninoff, Christophe Tron, Pierre-Yves Litzler, Alan Zajarias, Brahim Baala, Damien Brunet, Alain Cribier, Rouen University Hospital, Rouen, France

Background: Trans-catheter aortic valve replacement using the Edwards - Sapien aortic valve is a promising alternative treatment for patients (pts) with severe aortic stenosis (AS) considered too high risk for conventional aortic valve replacement. Percutaneous heart valve (PHV) can be implanted using a trans-femoral or trans-apical route. The femoral approach requires the ilio-femoral arteries to be capable of receiving a 22 Fr or 24 Fr sheath for the 23 and 26 mm valve, respectively. Angiographic criteria for arterial suitability have not been fully defined.
Methods: The aim of the study was to evaluate the femoral and iliac arteries and further determine their adequacy for implantation of a PHV using an arterial route in pts with severe AS. 135 consecutive pts with severe AS (aortic valve area (AVA) $\leq$ 0.8cm^2) who underwent diagnostic angiography from May 2006 to August of 2007 were prospectively included. Aortic angiography with ilio-femoral runoff was performed in all. Iliac and femoral artery transverse diameter were obtained. Vessel calcification and tortuosity were graded using a 4 point scale (0 = none, 1= mild, 2= moderate, 3= severe). Patients were considered candidates for the 23 mm valve if the minimal vessel diameter was $\geq$ 7 mm, calcification score was $\leq$ 2, and tortuosity score $\leq$ 2; or a 26 mm valve if the minimal vessel diameter was $\geq$ 8 mm, calcification score $\leq$ 2, and tortuosity was $\leq$ 2.
Results: Patients mean age was 81$\pm$8 years and 50% were female. Mean femoral artery diameter was 7.5 $\pm$ 1.3 mm and mean iliac artery diameter was 9.3 $\pm$ 2.3 mm. Tortuosity was $\leq$ 2in 72% of patients. Calcifications were $\leq$ 2 in 83%. Suitability for a 23-mm and 26 mm valve was achieved in 71% and in 39% respectively. Age and sex (< 80 vs. >80 yrs) did not influence candidacy based on the angiographic characteristics evaluated.
Conclusions: Trans-femoral implantation of Edwards- Sapien bioprosthesis appears feasible in 71% and 39% of pts requiring a 23-mm valve and 26-mm valve, respectively. Trans-apical implantation is an alternative for pts not meeting these criteria. Further technical improvements with smaller sheath requirements will increase candidacy.

4:00 p.m.

2209-11 Patent Foramen Ovale Closure in Patients Above the Age of 55 Years With Presumed Paradoxical Embolism

Christian Spies, Clifford J. Kavinsky, Rainer Schräder, Ziyad M. Hijazi, Rush University Medical Center, Chicago, IL, Cardioangiologisches Centrum Bethanien/ Markuskrankenhaus, Frankfurt, Germany

Background: Patent foramen ovale (PFO) is associated with cryptogenic stroke in patients younger than 55 years. PFO closure for cryptogenic thromboembolic events (TE) has been shown to be associated with low recurrence rates of TE. However, little is known about the recurrence rate of TE in patients above the age of 55 years undergoing PFO closure for presumed paradoxical embolism. We report our long-term experience of PFO closure in the subgroup of patients above the age of 55.
Methods: From 8/1994 until 09/2007 PFO closure was attempted in 423 patients (pts) above 55 years of age. Average age was 63 years (range 56-88) of which 195 (46%) pts were female. An atrial septal aneurysm was present in 196 pts (46%). Prior to PFO closure a total of 635 TE occurred (mean 1.5 events per patient). Indication for PFO closure was stroke (69% of pts.), transitory ischemic attack (TIA) (27%) or peripheral thromboembolism (4%). Implantation of the device was guided by fluoroscopy and transesophageal or intracardiac echocardiography under conscious sedation.
Results: A PFO occluding device was implanted successfully in all pts. Peri-procedural complications occurred in 12 (2.8%) pts (pericardial effusion=5, transient ST-segment elevation=2, access site complication=5). Follow-up information is available for 391 (92%) pts. Mean follow-up time was 28 months (range 0-129). Cumulative follow up time is 927 patient years. Complete closure during follow up was documented in 91% of pts. Following PFO closure, 17 recurrent TE (TIA=11, stroke=6) were recorded. This translates into an overall annual recurrence rate of 1.8% for TE (TIA=1.2%, stroke=0.6%). No major complications were noted during follow up.
Conclusion: PFO closure in elderly pts above 55 years of age is safe and efficient and seems comparable to those under the age of 55. Although traditional cardiovascular risk factors may be more frequent in this age group compared to those younger than 55 years, PFO closure should not be withheld as a possible therapeutic option in this age group.

4:45 p.m.

2209-13 Catheter Closure of Paravalvular Leaks

Nicolas Majunke, Ralph Hein, Nina Wunderlich, Horst Sievert, CardioVascular Center, Frankfurt, Germany

Background: Though surgery is the preferable option to treat paravalvular leak, it has a high mortality and morbidity. We present one of the largest series of patients who underwent transcatheter occlusion using the Amplatzer PDA, ASD or muscular VSD occluder.
Methods: A catheter occlusion of paravalvular leak has been attempted in 27 patients since June 2002. Heart failure and/or hemolysis were the most frequent symptoms among the patients. Mitral paravalvular regurgitation was present in 17 patients, aortic in 10. Seven patients had multiple defects.
Results: Successful device implantation was achieved in 24 of 27 patients. Immediate residual leak occurred in 88%. A symptomatic (clinical symptoms of haemolysis and/or symptoms of heart failure in combination with high velocity paravalvular jets or paravalvular regurgitation $\geq 2^{nd}$ degree) residual shunt during the period of follow up persisted in 10 patients (42%). Two major procedural complications occurred. In one patient the implant obstructed the prosthetic valve which later required surgery. Another patient died due to cardiac failure. Severe complications during follow up led to early death due to endocarditis accompanied by acute subarachnoid haemorrhage (n=1), acute renal insufficiency due to severe haemolysis (n=1) and surgical intervention (n=3; a severe haemolysis persisted or worsened post-procedurally). Another three patients underwent successful reintervention. Interventional success in terms of declining symptoms (objectified by NYHA class, echocardiography and haemolysis parameter) was achieved in fifteen patients (63%), including three patients that received a second procedure.
Conclusions: Though catheter closure of paravalvular regurgitation is technically feasible. However, it is associated with significant morbidity and mortality. Patients who are not suitable for a surgical correction should nevertheless be considered for catheter closure.

IV.SYMPOSIUM

2627

The Cardiovascular "Structuralist": Lessons in Structural Heart Disease

Monday, March 31, 2008, 3:30 p.m.-5:30 p.m.
McCormick Place, Room S103bc

4:10 p.m.

2627-7 The Relationship of the Coronary Sinus/Great Cardiac Vein to the Coronary Arteries and Mitral Annulus Allows for Percutaneous Mitral Annuloplasty in Most Patients: Data From the AMADEUS Trial

Richard Van Bibber, Uta C. Hoppe, Joachim Schofer, Michael Haude, Jean-Paul Herrman, Luz-Maria Rodriguez, Ludwik Firek, David G. Reuter, Steven L. Goldberg, Tomasz Siminiak, Cardiac Dimensions, Inc., Kirkland, WA

Background: It has been proposed that the relationship of the coronary sinus / great cardiac vein (CS/GCV) to the mitral valve annulus and neighboring coronary arteries may significantly limit the clinical applicability of percutaneous coronary sinus based mitral

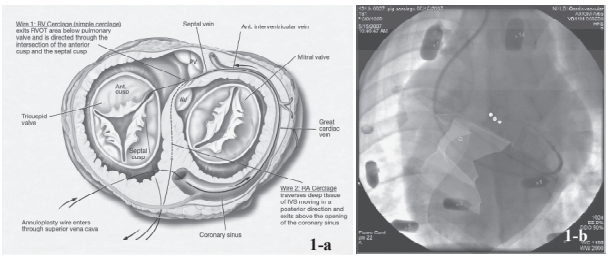
annuloplasty for functional mitral regurgitation (MR). Acute data from the AMADEUS™ trial of the CARILLON™ Mitral Contour System™ are reported and include MR reduction and the impact of the CS/GCV location and its relationship to the coronary arteries.
Methods and Results: Site-reported transesophageal echocardiography was used to determine intraprocedural reduction in MR. Percutaneous mitral annuloplasty in patients with MR and dilated cardiomyopathy resulted in acute MR reduction (grade 3.0±0.6 to 2.0±0.8, p<0.0001) and permanent implantation in 30 out of 43 patients. Additional measurements in 20 of the implanted patients showed reductions in vena contracta (0.69±0.29cm to 0.46±0.26cm, p<0.0001), effective regurgitant orifice area (0.33±0.17cm^2 to 0.19±0.08cm^2, p<0.005), regurgitant volume (40±20ml to 24±11ml, p= 0.01), and jet area/left atrial area (45±13% to 32±12%, p<0.0005). Coronary arteries were crossed in 36 patients (84%). Arterial compromise contributed to lack of implantation in 6 patients (14%). All implants causing an arterial compromise were recaptured and removed without complications and with a return to baseline flow. Multislice computed tomography was used to determine the distance between the CS/GCV and the mitral annulus. Measurements were made at three locations roughly corresponding to each scallop of the posterior leaflet (P3, P2, P1). There were no differences at any location between patients who demonstrated a reduction in MR (19.4±3.9mm, 18.7±4.3mm, 16.6±3.8mm) and those who did not (19.2±3.1mm, 17.9±4.6mm, 15.2±4.6mm).
Conclusions: The first multi-center trial of this percutaneous mitral annuloplasty device shows that acute MR reduction and permanent implantation are achievable in the majority of eligible patients. Arteries are crossed in most patients and without significant impact. The location of the CS/GCV relative to the mitral annulus does not determine effectiveness.

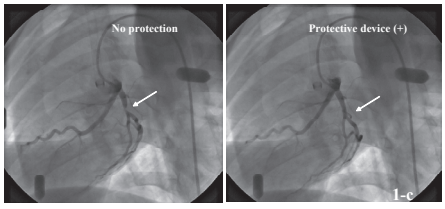
4:25 p.m.

2627-8 Novel Transcatheter Mitral Valve Cerclage Annuloplasty (MVCA) Attenuates Mitral Regurgitation and Preserves Entrapped Coronary Arteries

June-Hong Kim, Ozgur Kocaturk, Venkatesh K. Raman, Merdim Sonmez, Smita Sampath, Akin Yucetas, Cengizhan Ozturk, John A. Derbyshire, Michael A. Guttman, Ann H. Kim, Colin Berry, Elliot R. McVeigh, Robert J. Lederman, NHLBI, Bethesda, MD

Background: We developed MVCA to introduce circumferential tension around the mitral annulus and treat functional mitral regurgitation (MR).
Methods: MVCA entails coronary sinus guidewire access through a proximal septal brach of great cardiac vein using a deflectable microcatheter, followed by image-guided traversal of myocardium to reenter right heart chambers using two possible trajectories (Figure 1-a). The circle is closed by snare retrieval then applying and fixing graded tension interactively to reduce MR. A rigid implant was developed to protect entrapped coronary arteries against compression. Catheter trajectories were planned from segmented cardiac MRI roadmaps fused with X-ray fluoroscopy (XFM) to guide the procedure(Figure 1-b). MR was created by serial myocardial infarction. Endpoints included slice-tracking phase-contrast MRI, angiocardiography, and conductance pressure-volume loops. Results: MVCA was successful and attenuated mitral regurgitation in 14/16 swine that had suitable anatomy. MVCA reduced MR (regurgitant fraction of 22.8 ± 12.7 % in baseline vs 7.2 ± 4.4 % after MVCA, p=0.04) by reducing annular circumference, septal lateral distance(3.1 ± 0.3 cm in baseline vs 2.6 ± 0.4 cm after MVCA, p<0.01), and moving the line of coaptation without deleterious effect on LV contractility (Emax of 2.2 ± 1.3 mmHg/ml in baseline vs 2.6 ± 1.5mmHg/ml after MVCA). The protection device preserved distal pressure in entrapped arteries (Figure1-c). Conclusions : MVCA is feasible using simple catheter devices and XFM image guidance, and effectively abates functional MR in a porcine ischemic model.



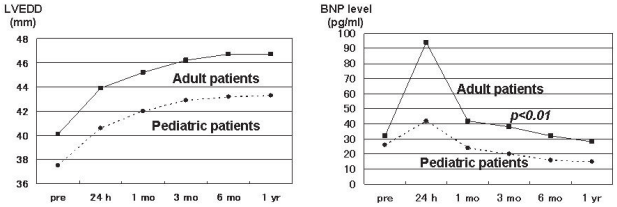


4:55 p.m.

2627-10 Difference of Cardiac Remodeling After Transcatheter Closure of Atrial Septal Defect Between Pediatric and Adult Patients

Teiji Akagi, Manabu Taniguchi, Shin-ichi Otsuki, Yoshio Okamoto, Yoshio Okamoto, Kengo Kusano, Shunji Sano, Okayama University, Okayama, Japan

Background: Although early cardiac remodeling after transcatheter closure of atrial septal defect (ASD) have been reported, the difference of remodeling process between pediatric and adult patients is not clarified completely.
Methods: Depends on age at procedure, 62 patients were divided into 2 groups; pediatric group (n=27, mean age: 14.6± 5.8, range: 6-19 years) and adult group (n=35, mean age: 51.2±8.9, range: 40-75 years). Size of Amplatzer septal occluder (17.5±4.9 vs. 20.2±4.1mm), Qp/Qs ratio (2.33±0.6 vs. 2.5±0.63) and mean pulmonary arterial pressure (13.8±2.5 vs. 15.9±5.6 mmHg) were not statistically different between 2 groups. Transthoracic echocardiography and plasma BNP level were evaluated before closure, 24 hours, 1, 3, 6 months and 1 year after the closure.
Results: Significant increased LVEDD, decreased RVEDD and RV/LV ratio were observed in both groups. Degree and time course of these changes were not statistically different between 2 groups. Significant elevation of BNP level was observed at 24 hours after the closure then decreased gradually in both groups. However, the peak BNP elevation was significantly higher in adult group compared to pediatric group. (Fig.)
Conclusions: Our data suggested that significant cardiac remodeling can be expected in adult patients (even if their age >40 years) as same as pediatric population. However, intrinsic changes may be different between adult and pediatric patients, which were shown by significant difference of BNP transition.



5:10 p.m.

2627-11 Long-Term Results of Percutaneous PFO Closure in 720 Patients

Eustaquio Onorato, Francesco Casilli, Marco Berti, Gian Paolo Anzola, S. Orsola Hospital, Fatebenefratelli, Brescia, Italy

Purpose: To assess the outcome of catheter closure of patent foramen ovale (PFO) with different PFO occluder devices (ODs) in pts with ischemic cerebral events due to presumed paradoxical embolism Methods: Between June 1999 and June 2007, 720 pts aged 48±15 years (range 14-75) underwent PFO closure. Indications for PFO closure were based on international guidelines. Pre-procedurally thromboembolic events (ThEE) were: 333 ischemic strokes (46%), 430 TIA (60%), 46 peripheral or coronary arterial embolism (6.4%). 6 pts suffered from platypnea-orthodeoxia syndrome or refractory hypoxemia. The procedures were performed with local anaesthesia under fluoroscopic and Intracardiac Echocardiographic (ICE) guidance. Antiplatelet therapy was given for 6 months. Results: 724 devices (645 Amplatzer PFO Occluder; 7 GORE Helex Septal Occluder; 4 PFO Star X, 52 CARDIA *I*ntrasept and 16 St Jude Premere PFO System) were placed correctly in all pts. During the follow-up period some major complications occurred: 1 early death due to massive pulmonary thromboembolism (PTE) and 5 late deaths (respiratory failure, PTE, sudden death and one case of suicide); severe pericardial effusion (1 case); partial epileptic disorder (3 cases) and transient cerebral ischemia (3 cases). Paroxysmal atrial fibrillation was recorded in 14 pts (1.9%). Thrombosis on the right side of the OD was observed in 1 patient affected by hypercoagulable state (LAC) despite anticoagulation therapy. A significant residual right-to-left shunt (RLS) was found in 5 pts by ce-TCD who received a second ODs abolishing the residual RLS. No device embolization, infective endocarditis, fatal stroke and/or major stroke occurred. Conclusions: PFO catheter closure is safe and effective. Long-term echocardiograpic evaluation is mandatory in pts with prothrombotic states. The combination of ICE imaging and ce-TCD represents a major advance in interventional cardiology for successful deployment of ODs, avoiding the need of transesophageal echocardiography and general anaesthesia or sedation. Long-term follow-up results appear favourable with respect to recurrent ThEE.